REMARKS

The present application contains claims 143-158, 200-205 and 219-248. Claim 143 was amended to add a missing "a" and claims 151, 152, 153 and 155 to correct an antecedent problem, as discussed below. Claims 219-248 are new. Claims 219-226 find support at least on page 83, lines 23-29 of the application as filed. Claims 227-245 find support in the description at least on pages 83-86. Particularly, claim 227 finds support, for example, on page 83, lines 11-20. Claims 228-229 find support at least in Figs. 12A and 12B and their description. Claim 230 finds support at least on page 86, lines 6-8. Claim 232 finds support at least on page 83, lines 20-21 and Fig. 12B. Claims 246-248 find support at least on page 38, lines 5-33. It is noted that the use of various embodiments in the kits of Figs. 12 is suggested on page 87, lines 9-16 and page 90, lines 3-6.

Applicants suggest amendment of Figs. 12A and 12D as in the attached drawing sheets, in which reference numbers 500 and 482 were added.

The drawings and claims 143-158 were objected to for not showing and enabling "the distal portion of the outer tube has an outer diameter substantially the same as an outer diameter of the punch element" as claimed in claim 143. Applicants respectfully traverse the rejection.

The requirement that "the distal portion of the outer tube has an outer diameter substantially the same as an outer diameter of the punch element" is shown, for example, in Figs. 12K and 12L. In the embodiment of these Figures, the distal portion (at the bottom of the page) of the outer tube 513 has a sharp shape such that its outer diameter is substantially equal to the outer diameter of the punch element 650. The substantially equal outer diameters allows easy entrance of the outer tube into the blood vessel through the hole punched by the punch element, as shown, for example, in Figs. 12Q and 12R.

The Examiner's note that if the outer diamcters of the punch element and the outer tube are the same then the punch element will not fit in the outer tube is correct, but the claim uses the term "substantially" to compensate for the small difference between the outer diameters. Applicants are of the opinion that this difference is unimportant to the person of the art, relative to the knowledge that the punch element fits snugly in the distal portion of the outer tube such that the outer tube can sever blood vessel tissue. This is the reason that applicants did not amend claim 143. Applicants,

however, would be willing to amend the claim to use the term "similar size" or an equivalent term, if the Examiner feels such amendment is necessary. In view of this discussion, applicants submit that the statement at issue is enabled, described and shown in the figures.

The drawings and claim 154 were objected to for not showing and enabling "wherein the punch element is radially expandable from a first small diameter to a second working diameter" as required by claim 154. Applicants respectfully traverse the rejection.

The requirement that the punch element is radially expandable is shown in Figs. 12S and 12T and is discussed on page 86, lines 9-28. The depression is shown in Figs. 12Q and 12R and is discussed on page 85, lines 20-27. The combination of these two requirements in a single apparatus is suggested at least on page 90, lines 4-6, of the application and would be straight forward to those skilled in the art after reading the specification of the present application. Regarding enablement, the expanding of the punch element is suggested in one embodiment to be performed by a balloon (page 86, lines 15-17). At least this embodiment could be easily combined with the depression by those skilled in the art.

The requirement that the drawings show every feature of the invention does not require that each combination of features be shown by the figures, as showing all the claimed combinations would require many more figures and would make the size of the application enormous. Applicants note, however, that if agreement is achieved regarding enablement, applicants will agree to provide another figure.

Claims 151, 152, 153 and 155 stand rejected due to lack of antecedent for the term "said distal end". Claims 151, 152, 153 and 155 were amended to correct "distal end" to "distal portion" in accordance with the language of claim 143.

Claims 143-158 stand rejected under 35 U.S.C. §102(e) or §103(a) as being unpatentable in view of Gifford (US patent 5,695,504) or Gifford in combination with Yang (5,989,287). Applicants respectfully traverse the rejection.

Claim 143 requires a punch element having a sharp tip suitable for penetrating a blood vessel. The tip of cutter anvil 136 of Gifford is clearly seen as having an obtuse angle (Figs. 5A and 5B). In the description, the tip of cutter anvil 136 is not used to penetrate a blood vessel, but rather a slit is made in the blood vessel and cutter anvil 136 is inserted through the slit (col. 18, lines 60-64). The anvil 136 is used to center the

stapling mechanism 119 around the attachment point and to support the wall of the target vessel to allow the cutter 137 to cut the vessel wall (col. 18, lines 64-66, and col. 19, lines 4-20).

Claim 143 further requires a depression of a size adapted to receive a blood vessel such that a blood-proof seal is formed between the vessel and the depression. Gifford, on the other hand, does not have a depression of a size adapted to receive the blood vessel. The depression 135 (Fig. 5A) to which the Examiner refers, is much longer than the blood vessel wall 150 and therefore would not prevent blood leakage.

Applicants submit that absent either of the above claim requirements the Examiner has not established a *prima facie* case of anticipation. Applicants note that there would be no reason to change the size of the depression to prevent blood leakage when a slit is made by a separate cutter, since blood would spurt out already at the time of cutting the slit.

The dependent claims are patentable at least because they depend on an allowable claim. At least some of the dependent claims add further patentablitiy over Gifford. Claim 150, for example, requires a valve for preventing blood from leaking out of said outer tube once the punch element is removed. Neither Gifford nor Yang describe such a valve. In fact, the Examiner only rejected claim 150 with regard to formal requirements. In view of the above remarks, applicants request that the Examiner indicate claim 150 as allowable. In addition, new claim 219 presents in independent form the subject matter of claim 150, without unnecessary limitations of the parent claim 143. Applicants request that the Examiner indicate claim 219 and its dependent claims 220-226 as allowable.

Applicants note that claims 154 and 155 were also only rejected due to formal issues and therefore are allowable in view of the above discussion of the formal matters.

Claims 200-205 stand rejected under 35 U.S.C. §102(e) as being anticipated by Gifford (US patent 5,695,504). Applicants respectfully traverse the rejection. Claim 200 requires transporting a tool across a wall of a blood vessel transfixed by a hole puncher through a lumen of the hole puncher. While applicants acknowledge that Gifford shows bringing a graft through a lumen of a hole puncher (Fig. 5F, Gifford), Gifford does not teach or suggest transporting a tool across a wall of the vascular system. Gifford in Figs. 5A-5G and 17A-17D (column 25, lines 50-53) shows the use of a two piece staple, a first piece being attached to the wall before the punching (and being mounted on the

punch before hand so that it does not pass through a lumen of the punch) and a second piece (102, 209) which is passed through a lumen of the stapling mechanism. The second piece, which is passed through the lumen of the stapling mechanism, does not pass across the wall of the blood vessel, as required by claim 200.

In the one part anastomosis connector embodiment, a special staple 163 is used with a separate aortic punch (column 23, lines 62-65).

At least some of the dependent claims add further patentability over Gifford. New claim 230, for example, requires that the removed sub-assembly include a hole making pin but not a protective sleeve surrounding the hole making pin. Gifford does not have a hole making pin. The cutter anvil 136, however, is removed with the vessel punch cutter 137 as is clearly seen from a comparison of Figs. 5D and 5E of Gifford.

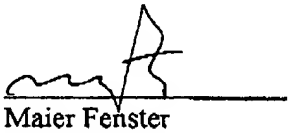
Claim 232, for example, requires removing the sub-assembly while an extension of the hole puncher remains within a hole defined around the removed portion of the wall. As can be seen in Fig. 5E of Gifford, in Gifford only the staple remains in the wall and even the staple does not remain in the hole. In addition, the staple is not an extension of the hole puncher.

New independent claim 233 also relates to providing a connector to a blood vessel. Claim 233 requires transporting a connector including at least one spike through a lumen of a hole puncher. Gifford does not teach or suggest such an act.

New independent claim 240 presents in independent form the act of claim 230, without unrequired limitations of the parent claim. Claim 240 requires removing a tissue engager from a channel of a hole puncher, while a surrounding sheath remains in the vicinity of the blood vessel. As discussed above, this is not taught or suggested by Gifford.

In view of the above remarks, applicants submit that the claims are patentable over the prior art. Allowance of the application is respectfully awaited. If the Examiner is unable to agree that the elected claims are all patentable, he/she is respectfully requested to contact the undersigned at toll free 1 (877) 428-5468. This number connects directly to our office in Israel. Please note that Israel is 7 hours ahead of Washington and that our work week is Sunday-Thursday.

Respectfully Submitted,
Ari DEROWE et al.



Maier Fenster
Reg. No. 41,016

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William H. Dippert, Esq.
Reed Smith LLP
599 Lexington Avenue, 29th Floor
New York, NY 10022-7650

Tel: (212) 521-5400